

Infection-Related Root Cause Analysis

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Joint Commission Resources



Client name/ Presentation Name/ 12pt - 1

Objectives

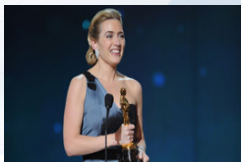
- Describe and identify Sentinel Events (SE)
- State the steps in performing a Root Cause Analysis (RCA) process
- Compare steps in RCA, outbreak investigations, and performance improvement methodology
- Discuss one example of an infection-related RCA



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I'd like to acknowledge and thank...

Denise Murphy, VP Quality, Main Line Health System



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What is a Sentinel Event?

- “An unexpected occurrence involving death or serious physical or psychological injury or risk thereof.”



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Examples of Sentinel Events

- Death resulting from a medication error or other treatment related error
- Suicide of a patient in a setting where they receive around-the-clock care
- Surgery on the wrong patient or body part regardless of the magnitude of the operation
- Hemolytic transfusion reaction involving the administration of incompatible blood or blood products
- Infection-related death or permanent disability



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What is Root Cause Analysis?

- A process for identifying the basic or causal factors that underlie variation in performance.
- This process should be used to identify risks that led to a sentinel event (SE)



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Why the Focus Now?

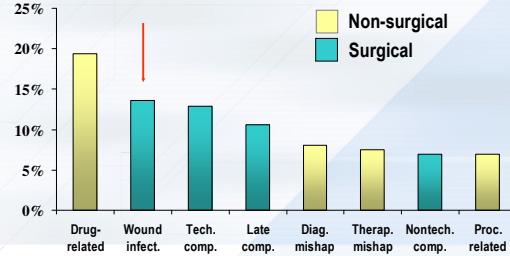
- Institute of Medicine report on the Quality of Healthcare in America (1999)
 - In 1997 more Americans died because of medical error than because of auto accidents (43,458), breast cancer (42,297), or AIDS (16,516).
- The Harvard Medical Practice Study (1984)*
 - 98,609 adverse events, 27,179 of which were due to negligence
 - 2,550 suffered permanent total disability
 - 13,451 died, at least in part as a result of the adverse event
- The Colorado and Utah Study (1992)
 - In 1992, an estimated 5,614 adverse events occurred in Utah and 11,578 in Colorado.



In-patients only*

Client name/ Presentation Name/ 12pt - 13

Proportion of Adverse Events Harvard Medical Practice Study



Source: Brennan et al. N Engl J Med. 1991; 324:370-376

Why include IC in NPSG?

- CDC estimates 2 million patients/year are infected
- Approximately 99,000 die (1 death every 6 minutes)
- Cost over \$4.5 -6.0 billion
- 250,000 central venous catheter-related bloodstream (CRBSI)/year
 - Attributable mortality 12%-25%
 - \$25,000 per episode



Thanks Teresa

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What do IPs bring to the RCA process?



What do IPs bring to the RCA process?

- Ability to investigate outbreaks and identify risk factors associated with infectious events
- Data collection, organization, analysis
- Familiarity with use of standards and prevention guidelines
- Experience in literature search
- Working with multidisciplinary teams



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What happens once the IP identifies a potential SE?

- The organization must complete a *credible* root cause analysis within 45 days of the event.
- The Joint Commission has created a framework to use to make sure all elements are addressed (Attachment A)*
- A multidisciplinary team should tackle each of these content areas to help identify contributing factors, identify root cause, and put effective control measures in place to reduce the risk of recurrence.
- Include Patient Safety, Risk Mgt. & Performance Improvement experts!



Source: Framework for Investigating Infection-related Sentinel Events
www.apic.org

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Identifying HAI-related Sentinel Events

- Work with medical records dept. to identify all deaths
- Compare hospital deaths with your HAI database to identify potential HAI-related deaths
- Work with hospital epidemiologist or ICC chair to review chart; determine if death or disability is “unanticipated”
- Know expected mortality rate associated with type of infection
 - e.g., patients with VAP have a highly anticipated mortality rate (up to 60%); may be hard to consider VAP death as unanticipated
 - patients having elective surgery with few risk factors for SSI are not expected to die of SSI-related infection
- Unanticipated deaths should be considered SE and must be investigated

Steps in Root Cause Analysis



Step One: Organize a Team

- Leader(s) lay the groundwork
 - Identification and reduction of risks
 - Processes vs. individuals – no blame
- Multidisciplinary – (10 or less)
 - May include ad hoc members

Step 1

- May be a new or already existing team
 - Individuals closest to the event
 - Individuals critical to implementation of recommendations
 - A respected & credible leader
 - Individuals with diverse knowledge base
 - (& PI / PS experience)

Step 1

- First Team Meeting
 - Establish ground rules
 - Decision making
 - Attendance
 - Meeting schedule
 - Opportunity to speak
 - Disagreements
 - Assignments

Step 2: Define the Problem

- Describe what happened
 - Focus on **what** happened not why it happened
 - Verbalize accurately and succinctly
 - “Mrs. Jones was a 55 y/o pt. who underwent elective CABG procedure. She had a cardiac arrest and died on her third post-op day. No signs of SSI. Sepsis was found confirmed by blood cultures and autopsy. Central line sepsis suspected.”

Step 3: Study the Problem

- Collect information related to the event or possible event
 - Witness statements of those directly & indirectly involved
 - Observations
 - Physical evidence (purulent secretions at CVC insertion site)
 - Documentary evidence (“pus noted at insertion site” in progress note)

Step 3

- Information format
 - Written documentation
 - Audiotape
 - Photographs
 - Videotape (may be intimidating)

Step 4: Determine What Happened

- Flowchart the sequence of the event
 - First, chart the actual sequence of events
 - Then flowchart the ideal sequence of events (highlight the differences)
 - Flowchart the steps in the policy/procedure
 - Compare the gaps

Step 4

- Create a timeline of the events

| TIME | EVENTS | ACTIONS |
|--------|--|---|
| 4/1/04 | Patient underwent CABG surgery CVC placed in PACU | Patient transferred to CTICU |
| 4/2/04 | CVC functioning, site looks clean, no S&S infection | |
| 4/3/04 | Patient transferred to step down unit at 1800 | ICU RN pulled line out prior to transfer to step down unit. Pus noted at insertion site. Alebrile |
| 4/4/04 | Pt. developed fever and shaking chills at 0500 Nurse found patient unresponsive, no pulse or respirations at 0655 | Attending notified, blood cultures ordered and drawn at 0540. Antibiotics started 0620. Code called 0656 |
| | CPR started by nurse at 0658; Patient expired 0800 | |

Step 5: Identify Contributing Process Factors

- Why did the event occur?
 - Which processes were involved in the event or could have lead to the event? (brainstorming, affinity diagrams)
 - What are the steps in the process as designed? (flowchart of policy/procedure)
 - Which steps may have contributed to the event?

- Continue asking why the event occurred?
 - What is currently done to prevent failure at this step? (fault tree analysis)
 - Was it done? (barrier analysis)
 - If not, why?
 - What additional services/departments are effected?

TRIGGERS

The diagram illustrates a progression of defenses from Institution to Technical. A globe icon is positioned next to the 'Institution' label. A red starburst labeled 'ACCIDENT' is at the end of the progression. The progression is shown as a series of overlapping planes, each with circles representing vulnerabilities. The labels for the planes are: Institution, Organization, Profession, Team, Individual, and Technical. The triggers for each stage are: Lack of Procedures, Punitive Policies, Mixed Messages, Zero Fault Tolerance, Sporadic Training, Clumsy Technology, and Deferred Maintenance.

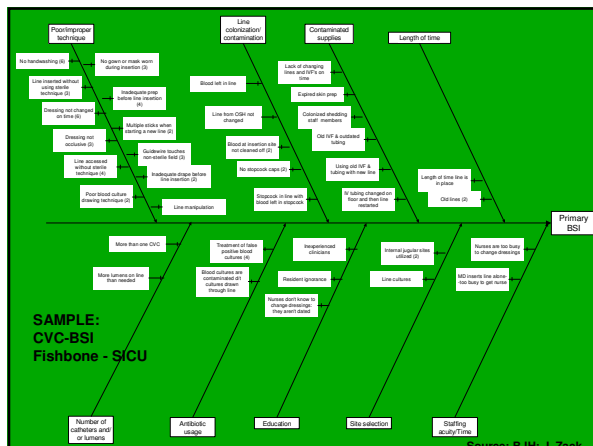
DEFENSES

Minimal Scope of Root Cause Analysis for Specific Types of Sentinel Events (see next slide)

[illegible]

Figure I-1. This matrix indicates those areas requiring inquiry when conducting a root cause analysis for a specific sentinel event.

[illegible]



Step 7: Measure - Collect & Assess Data (Proximate and Underlying Causes)

- Baseline data – *is this a one time event or a trend?*
- Measure a process or step in a process
- Assess effectiveness of improvement interventions
- Measurements should be rate-based
 - % central lines placed in femoral sites
 - CVC-BSI/1,000 line days in CTICU

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Step 8: Design and Implement Interim Changes

- Fix low hanging fruit
- Create a timeline, Gantt chart or implementation tree to help the team & administration view key steps and time frames needed to complete each step

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Step 8: Design and Implement Interim Changes

– Example Gantt Chart

| ID | Task Name | Start | Finish | Duration | Feb 2002 | Mar 2002 | Apr 2002 |
|----|---|-----------|-----------|----------|----------|----------|----------|
| 1 | Fix the overhead light to maintain position | 2/6/2002 | 2/6/2002 | 2w | | | |
| 2 | Analyze current data for BSE in the OR | 2/13/2002 | 2/21/2002 | 1.4w | | | |
| 3 | Determine data to be collected, when & by whom? | 2/21/2002 | 2/28/2002 | 1.2w | | | |
| 4 | Develop data collection tool | 3/1/2002 | 3/8/2002 | 1.2w | | | |
| 5 | Instruct data collectors re: use of tool | 3/18/2002 | 3/20/2002 | .6w | | | |
| 6 | Data collection | 3/20/2002 | 4/19/2002 | 4.6w | | | |
| 7 | Data Analysis | 4/22/2002 | 4/30/2002 | 1.4w | | | |
| 8 | Review findings with the team | 5/1/2002 | 5/1/2002 | .2w | | | |

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Step 9: Identify Which Systems Are Involved The Root Causes

- Identify the underlying causes for the **proximate** causes (using BSE example)
 - Why did the nurse wait to report the sharps injury until the end of the shift?
 - Why did the nurse not know a sharp was being handed to her?
 - Why hadn't the nurse completed orientation?

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The Root Causes

- May involve multiple root causes
- Drill down using the flowcharts, fishbone, barrier analysis, FMEA or fault tree analysis
- May include factors beyond the organizations control (e.g., nursing shortage)

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The Root Causes

| Proximate Cause | Underlying Cause |
|--|--|
| Delay in reporting needle stick until the end of the shift | RN hadn't completed last two weeks of orientation & was unfamiliar with the policy re: reporting BSE immediately |
| Lack of clear communication when passing sharp | Physicians not trained on policy to 1st announce intent to pass sharp |

Five Rules of Causation*

(*Adapted from David Marx)

- 1 - Causal statements must clearly show the "cause and effect" relationship.
- 2 - Negative descriptors (e.g., poorly, inadequate) are not used in causal statements.
- 3 - Each human error must have a preceding cause.
- 4 - Each procedural deviation must have a preceding cause.
- 5 - Failure to act is only causal when there was a pre-existing duty to act.

Step 10: Prune the List of Root Causes

Ask three questions to each cause

- Would the problem have occurred if Cause #1 had not been present?
- Will the problem recur due to the same causal factor if Cause #1 is corrected or eliminated?
- Will correction or elimination of Cause #1 lead to similar events?



Step 11: Confirm Root Causes

- Literature review
 - Risk – reduction strategies
 - System approach do not blame individual (s)
 - Each stage of system development
- Error prevention strategies
 - Systems should be designed to absorb errors
 - Look to "mistake-proof" when possible

Step 12: Explore & Identify Risk-Reduction Strategies

- Failure Mode & Effects Analysis (FMEA)
 - Look at the steps in the process
 - Flow chart the process, predict where risk or "failure modes" exist and redesign process to eliminate risk

What is Failure Mode & Effects Analysis (FMEA) ?

- “A prospective assessment that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome.
- “A systematic approach to identify and prevent product and process problems before they occur.”

Step 12: Explore & Identify Risk-Reduction Strategies

- Determine the severity of potential cause
 - **Catastrophic** – death, suicide, rape,
 - **Major** - permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement
 - **Moderate** – increased length of stay
 - **Minor** – near miss

Step 12 FMEA

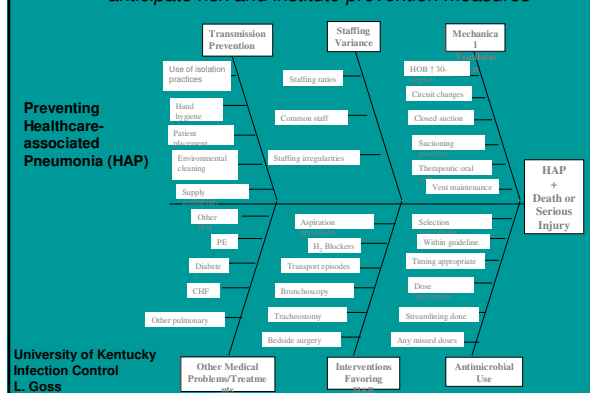
- Determine the probability of the *potential* cause or risk
 - **Frequent** - Likely to occur immediately or within a short period
 - **Occasional** - Probably will occur (may happen several times in 1 to 2 years)
 - **Uncommon** - Possible to occur (may happen sometime in 2 to 5 years)
 - **Remote** - Unlikely to occur (may happen sometime in 5 to 30 years)

Step 12

Failure Mode & Effect Analysis Hazard Scoring Matrix

| Probability | Severity | | | | |
|-------------|------------|--------------|-------|----------|-------|
| | | Catastrophic | Major | Moderate | Minor |
| | Frequent | 16 | 12 | 8 | 4 |
| | Occasional | 12 | 9 | 6 | 3 |
| | Uncommon | 8 | 6 | 4 | 2 |
| | Remote | 4 | 3 | 2 | 2 |

FMEA: BEFORE a sentinel event occurs, anticipate risk and institute prevention measures



Step 12

Design a system to absorb errors

- Standardize procedures
- Reduce variation
- Training & re-training
- Competency assessments
- Create a safe reporting environment

Step 13: Formulate Improvement Actions

- Directed at processes
- Tools
 - Brainstorming
 - Flowchart
 - Cause & effect diagram (Fishbone)

Step 14: Evaluate Proposed Improvements

- Rank the ideas based on the criteria
 - Individuals rank each idea best to worst (1-5)
 - Then consolidate into team ranking
- Are improvement actions objective and measurable?
- Ensure team reaches consensus
- May rank according to multiple criteria
 - Cost, risk, implementation time, etc.

Step 14

- Each selected improvement action should:
 - Address a root cause
 - Offer a long-term solution to the problem
 - Offer more positive than negative impact on other processes (no negative ripple effect)
 - Objective and measurable
 - Defined implementation time
 - Have assigned accountability

Step 15: Design Improvements

- What?
 - Determine scope of actions
- How?
 - Sequence of events
 - Measurement – quantitative
- When?
 - Timeline for implementation
- Who?
 - Who owns the process – initially & eventually
- Where?
 - Clarify where each action will be implemented

Step 16: Ensure Acceptability of Action Plan

- Acceptable to the Joint Commission if:
 - Focuses primarily on systems and processes, not individual performance
 - Identifies who is responsible for implementation
 - Identifies when actions will be implemented (including pilots)
 - Identifies how the actions will be evaluated (measurement)

Step 17: Implement the Improvement Plan

- Scientific Method
 - Plan, test, study, implement
- PDSA
 - Plan, Do, Study, Act

Step 18: Develop Measures of Effectiveness

- Collect Data
 - Team is responsible for measurement
 - Bring in organization experts (RM, PI, QI, Analyst) to design
 - Is software available?
 - Information management resources

Step 19: Evaluate Implementation Efforts

- Data analysis & presentation
 - Internal comparisons – before & after
 - Run chart, control chart, histogram
 - External comparisons – benchmarking
 - Practice guidelines/parameters
 - Performance targets, specifications or thresholds
 - NHSN, other professional organizations

Step 20: Take Additional Steps

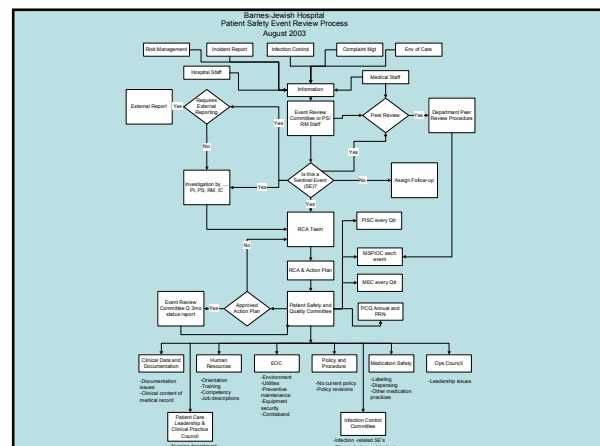
- If meeting goals –
 - Communicate the results
 - Revise processes or procedures
 - Complete training related to new policies, processes, procedures, documentation tools, etc.
 - Plan for continued monitoring
 - Roll our improvements to other areas
 - Radiology
 - Laboratory

Step 20

- If NOT meeting goals –
 - Ask if improvement was fully implemented
 - Leadership involvement - sponsorship
 - Communication gaps
 - Confirm the root causes
 - Identify risk reduction strategy
 - Plan for continued monitoring
 - Roll our improvements to other areas
 - Radiology
 - Laboratory

Step 21: Communicate the Results

- Communication is key **THROUGHOUT** the RCA process
 - Sponsorship
 - Departments/services impacted by changes (proposed changes)
 - New or revised policies
 - Celebrations/recognition for team



| FOCUS-PCCA | Steps in Preparing for a Root Cause Analysis | | Outbreak Investigation |
|--------------------------------------|--|--|---|
| Find an opportunity | | | |
| Organize a Team | Step 1 | Organize a Team | 1. Confirm existence of outbreak |
| | Step 2 | Define the Problem | 2. Confirm diagnosis of cases |
| Clarify the current process | Step 3 | Study the Problem | 3. Prepare or investigation |
| | Step 4 | Determine What Happened | 4. Create case definition |
| Understand variation | Step 5 | Identify Contributing Process Factors | 5. Search for additional cases |
| | Step 6 | Identify Other Contributing Factors | 6. Characterize epidemic by person, place, time (line list) |
| | Step 7 | Measure - Collect and Assess Data on Proximate and Underlying Causes | 7. Generate tentative hypothesis |
| | Step 8 | Design and Implement Interim Changes | 8. Test hypothesis |
| | Step 9 | Identify Which Systems Are Involved - Root Causes | 9. Institute additional studies |
| | Step 10 | Prune the List of Root Causes | 10. Implement interventions |
| Select the improvement solution | Step 11 | Confirm Root Causes | 11. Communicate findings |
| | Step 12 | Explore and Identify Risk Reduction Strategies | 12. Move to process improvements |
| Plan the improvement | Step 13 | Formulate Improvement Actions | |
| | Step 14 | Evaluate Proposed Improvement Actions | |
| | Step 15 | Design Improvements | |
| | Step 16 | Ensure Acceptability of the Action Plan | |
| Do the improvement, and collect data | Step 17 | Implement the Improvement Plan | |
| Check and study the results | Step 18 | Develop Measures of Effectiveness and Ensure Their Success | |
| | Step 19 | Evaluate Implementation of Improvement Efforts | |
| Act and hold the gain | Step 20 | Take Additional Action | |
| | Step 21 | Communicate the Results | |



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- <http://www.jcaho.org/sentinel/sentevent.htm>
- SE Policies & Procedures
- Root Cause Analysis Matrix
- Sentinel Event Statistics
- Glossary
- Links to other sites



Client name Presentation Name! 12pt - 68

Joint Commission RCA Questions

- **Questions**
- What happened?
- What are the details of the event? (Brief description)
- When did the event occur? (Date, day of week, time)
- What area/service was impacted?
- Why did it happen? The process or activity in which the event occurred.
- What are the steps in the process, as designed? (A flow diagram may be helpful here)
- What were the most proximate factors?
- What steps were involved in (contributed to) the event? Typically "special cause" variation) Human factors
- What human factors were relevant to the outcome? Equipment factors
- How did the equipment performance affect the outcome? Controllable environmental factors
- What factors directly affected the outcome? Uncontrollable external factors Are they truly beyond the organization's control?
- Are there any other factors that have directly influenced this outcome?
- What other areas or services are impacted

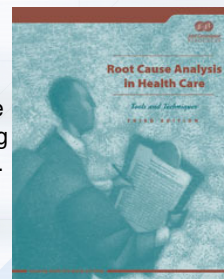


Client name Presentation Name! 12pt - 69

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This publication is to provide health care organizations with the "how to" of conducting a root cause analysis.

Describes "how to" conduct each of the twenty-one steps.



Client name Presentation Name! 12pt - 70

Ask "Why" Five Times to Get to the Root Cause

This story originally appeared in the Institute for Healthcare Improvement's electronic newsletter, Continuous Improvement.

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Failure Modes and Effects Analysis (FMEA) Tool (IHI Tool)

Failure Modes and Effects Analysis (FMEA) Tool (IHI Tool)


Background

Failure Modes and Effects Analysis (FMEA) was developed outside of health care and is now being used in health care to assess risk of failure and to prevent failures before they occur. This tool is particularly useful in identifying the most important areas for process improvement. FMEA has been used by hundreds of hospitals in a variety of Institute for Healthcare Improvement programs, including Idealized Design of Medication Systems (IDMS), Patient Safety Collaboratives, and Patient Safety Systems.



Thank You

– Questions?

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